

June 2, 2003

Richard Henrich
Manager, Regulatory Affairs
Great Lakes Chemical Corporation
Highway 52, N.W.
West Lafayette, IN 47996

Dear Mr. Henrich:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Ethyl Bromide posted on the ChemRTK HPV Challenge Program Web site on January 27, 2003. I commend the Great Lakes Chemical Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Great Lakes Chemical Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Ethyl Bromide

Summary of EPA Comments

The sponsor, Great Lakes Chemical Corporation, submitted a test plan and robust summaries to EPA for ethyl bromide (CAS No. 74-96-4) dated December 13, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 27, 2003. The sponsor also provided information on the analog, methyl bromide (CAS No. 74-83-9).

EPA has reviewed this submission and reached the following conclusions:

1. Analog Justification. The submitter has adequately supported the use of data on the analog methyl bromide to address health and ecotoxicity data gaps.
2. Physicochemical Properties. The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.
3. Environmental Fate. The submitter needs to provide photodegradation and biodegradation data for ethyl bromide and not for methyl bromide. The data provided by the submitter in the test plan for stability in water (hydrolysis) and transport and distribution (fugacity) are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to incorporate the hydrolysis and fugacity data into the robust summaries. The submitter also needs to provide the values used as inputs into its fugacity model.
4. Health Effects. All SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program. However, the submitter needs to provide robust summaries for the reproductive/ developmental toxicity data on methyl bromide.
5. Ecological Effects. The data are adequate for fish and invertebrates but not for algae. The submitter can either provide adequate existing algal toxicity on methyl bromide or conduct testing on ethyl bromide.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Ethyl Bromide Challenge Submission

Analog Justification

The submitter provides adequate information and justification for the use of methyl bromide as an analog for ethyl bromide for most endpoints on the basis of structure-activity relationships and physical/chemical properties. EPA agrees with this approach.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for stability in water and fugacity are adequate for the purposes of the HPV Challenge Program. However, the submitter needs to incorporate the hydrolysis and fugacity data into the robust summaries. The submitter also needs to provide the values used as inputs into its fugacity model.

Photodegradation. The submitter did not provide adequate photodegradation data for ethyl bromide. In the test plan the submitter provides an estimated half-life of 46 days; however, it is not clear whether this information is for ethyl or methyl bromide. Using data for methyl bromide as an analog is not acceptable in this case because estimated photodegradation data for ethyl bromide are readily available and are acceptable for the purposes of the HPV Challenge Program. The submitter needs to provide the details of this estimation in robust summary format.

Biodegradation. The submitter provides information on microorganisms that can degrade ethyl bromide (Janssen et al. 1987; Belay and Daniels, 1987; and Schwarzenbach et al. 1985), but does not provide any quantitative biodegradation data for the substance. The submitter also provided biodegradation data on methyl bromide. However, for these very small molecules, the difference of a single carbon may significantly affect the biodegradation rate. Furthermore, if data are available on the substance of interest, they are preferable to analog data. EPA located data for the biodegradation of ethyl bromide in a Japanese MITI test (Chemicals Evaluation and Research Institute, Japan; web page at http://www.cerij.or.jp/ceri_en/index_e4.shtml (February 19, 2003)) that appear to satisfy the endpoint for this substance. The submitter needs to include this information in the test plan and summaries.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

All SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

Reproductive/Developmental Toxicity. A two-generation inhalation reproductive toxicity study of methyl bromide in rats and inhalation developmental toxicity studies of methyl bromide in rats and rabbits adequately address this endpoint.

Ecological Effects (fish, invertebrates, and algae)

The fish and aquatic invertebrate data submitted on methyl bromide are adequate. No algal toxicity data were provided, however, and EPA disagrees with the submitter's contention that algal testing is not required. The submitter can provide valid existing test data on methyl bromide or conduct a 96-hour algal toxicity test with ethyl bromide according to OECD Guidelines.

Specific Comments on the Robust Summaries

Environmental Fate and Transport. The stability in water (hydrolysis) and transport and distribution (fugacity) data are adequate, but the submitter needs to incorporate these data into the robust summaries. The submitter also needs to provide the values used as inputs into its fugacity model.

Health Effects.

Reproductive/Developmental Toxicity. The submitter needs to provide robust summaries of the reproductive and developmental toxicity data on methyl bromide.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.